SUMMARY OF EXAMINER INTERVIEW

Applicants thank Examiner Nguyen for being available for, and participating in, a telephonic interview that occurred on October 8, 2009, in which the Applicants' representative discussed the rejections issued in the pending non-final office action. In particular, the Examiner described an approach to overcome the differences between the claimed invention and the references cited in support of the 35 U.S.C. § 102 and § 103 rejections of the independent claims. Specifically, the Examiner brought to the attention of the Applicants' representative that inventive aspects of the instant pending application should be discussed in a context of the current methods utilized in a hospital setting. This discussion is included in the Remarks section of this response.

REMARKS

The Non-Final Office Action mailed June 9, 2009, has been received and reviewed. Prior to the present communication, claims 1, 4, 6, 7, 9-12, 15-23, and 26-38 are pending in the subject application. All pending claims stand rejected. In particular, claims 4, 7, 9, 12, 15-22, 27, 30, 34, 35, and 38 stand rejected under 35 U.S.C. § 112, while claims 1, 4, 6, 7, 9-12, 15-23, and 26-38 stand rejected under 35 U.S.C. § 101. Further, claims 1, 6, 10, 11, 23, 26-29, 32, 33, and 36-38 stand rejected under 35 U.S.C. § 102(e), and claims 4, 7, 9, 12, 15-22, 30, 31, 34, and 35 stand rejected under 35 U.S.C. § 103(a).

As such, each of claims 1, 4, 7, 12, 23, 26-34, 36, and 38 has been amended herein, while no claims have been canceled or added. As such, claims 1, 4, 6, 7, 9-12, 15-23, and 26-38 remain pending. It is submitted that no new matter has been added by way of the present amendments. Reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Rejection to Amendment to Specification

In response to the rejection to the amendment to the Specification. The reference to paragraph [0012] of the pre-grant publication of the instant pending application is replaced by a reference to paragraph [0023] of the originally filed application. Accordingly, the changes to the paragraph [0023] are material to the merits of the instant pending application. Further, it is contended that the amendments to the paragraph [0023] are not new matter and inherent to the system for automatically conditioning a billing item.

Rejections based on 35 U.S.C. § 112

Claims 4, 7, 9, 12, 15-22, 27, 30, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph. In particular, the Examiner rejects claim 4 for reciting "supporting document," which

the Examiner asserts can include any data, such as hard copy data and computerized data. Along those lines, the Examiner believes that the Specification is enabling for searching computerized data, but not for searching hard copy data. Accordingly, claims 4, 7, 12, and 34 are amended to replace "supporting documentation" with "supporting computerized data."

Claims 34 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner asserts that the phrase "a plurality of computer software components" in claim 34 should not be given patentable weight. In response, this phrase is removed from claim 34. Also, the Examiner asserts that the scope of claim 38 cannot be ascertained. In response, claim 38 is amended to recite "the compliance template comprises the criteria necessary for qualifying." Accordingly, upon entering these amendments, claims 4, 7, 9, 12, 15-22, 27, 30, 34, 35, and 38 overcome the 112 rejections and are considered to be in condition for allowance.

Rejections based on 35 U.S.C. § 101

Claims 1, 4, 6, 7, 9-12, 15-23, and 26-38 stand rejected under 35 U.S.C. § 101 for being directed toward non-statutory subject matter. Initially, claim 1 stands rejected for reciting a system that includes a conditioning engine with no further structural limitations.

In response, claim 1 is amended to tie the conditioning engine to another statutory class. As amended, claim 1 recites a conditioning engine stored on a computing device (e.g., computer, machine, or other physical articles). The use of the tangible machine (i.e., computing device) imposes meaningful limits on a scope of the claim, and imparts patent-eligibility. Further, the involvement of the tangible machine in the claimed process is not merely

insignificant extra-solution activity, but serves to support the execution of the conditioning engine.

Accordingly, it is respectfully submitted that amended claim 1 is directed toward statutory subject matter. Further, claims 4, 6, 7, 9-11, 34, 37, and 38 are believed to be in condition for allowance based, in part, upon their dependency from independent claim 1, and such favorable action is respectfully requested.

Claim 12 is rejected for reciting a process that does not conform with the requirements stated in Bilski.[1] In response, the essential steps of the process are identified and amended to include a "computing device" for implementing those steps. The use of the tangible machine (i.e., computing device) imposes meaningful limits on a scope of the claim, and imparts patent-eligibility. Further, the involvement of the tangible machine in the claimed process is not merely insignificant extra-solution activity, but serves to support the implementation of the process.

Accordingly, it is respectfully submitted that amended claim 12 is directed toward statutory subject matter. Further, each of claims 15-22 and 35 are believed to be in condition for allowance based, in part, upon their dependency from independent claim 12, and such favorable action is respectfully requested.

Claim 23 is rejected for reciting "computer-readable storage media," which the Examiner considers to encompass nonstatutory subject matter. In response, as suggested by the Examiner during the examiner interview, claim 23 is amended to recite "tangible computer-readable storage media." Accordingly, it is respectfully submitted that amended claim 23 is limited to tangible embodiments and, thus, is directed toward statutory subject matter. Further,

[1] *Ex parte Bilski*, No. 2002-2257, 2006 WL 4080055, at *10.

claims 26-33 and 36 are believed to be in condition for allowance based, in part, upon their dependency from independent claim 23, and such favorable action is respectfully requested.

35 U.S.C. § 102 Anticipation Rejection based on U.S. Application No. 2003/0191667 to Fitzgerald

All pending claims 1, 6, 10, 11, 23, 26-29, 32, 33, and 36-38 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Application No. 2003/0191667 to Fitzgerald. As the Fitzgerald reference does not describe, either expressly or inherently, each and every element of the pending claims, as amended, Applicants respectfully consider the rejection overcome, as hereinafter set forth.

Independent claim 1, as amended hereinabove, recites a computer system comprising "*a conditioning engine stored on a processing unit*, the conditioning engine configured for receiving a preliminary billing item associated with a clinical event, analyzing, as a condition precedent to transmitting the billing item to a paying party, the preliminary billing item by comparison against a compliance template to determine compliance therewith" (emphasis added). In this way, the processing unit supports the operation of a conditioning engine that receives a preliminary billing item and automatically analyzes the preliminary billing item against a "compliance template."

The "compliance template" is now positively claimed as being part of the computer system because the compliance template is "temporarily stored on memory accessible to the processing unit." Further, the structure of the compliance template is claimed as the compliance template "*includes criteria configured based on the preliminary billing item and at least one regulatory guideline and comprises data fields*, which correspond to each of the criteria, respectively, that record information that satisfies the criteria, wherein the criteria, when

satisfied, qualify the preliminary billing item under the at least one regulatory guideline" (emphasis added). In this way, the criteria within the compliance template, which is used to determine if the preliminary billing item is compliant, is configured based on (a) the preliminary billing item and (b) at least one regulatory guideline. Further, as claimed, the compliance template must include criteria (e.g., criteria of compliance template 122 of FIG. 2 that includes physician referral, physician orders, etc.) that is dynamically selected based on, in part, attributes of the preliminary billing item.

In a substantially similar manner, independent claim 23, as amended herein, positively recites the compliance template as a structural element. Specifically, amended claim 23 recites, in part, "a compliance template," where "the compliance template includes criteria configured based on the preliminary billing item and at least one regulatory guideline and includes data fields, which correspond to each of the criteria, respectively, that record information that satisfies the criteria, wherein the criteria, when satisfied, qualify the preliminary billing item under the at least one regulatory guideline."

In the context of a hospital setting, a determination of whether a billing item is compliant with regulatory guidelines (e.g., established by an insurance company, Medicare, and the like) is a manual process that is so labor intensive that it is not performed for each bill when finalized for conveyance to a patient.[2] This high level of labor intensity is a due to the number and complexity of manual actions needed to determine compliance. For instance, a clinician would be required decipher the billing items (e.g., insurance account information, patient charts, physical orders, procedure codes, pharmaceutical prescriptions, anesthesiology or radiology

[2] *See* Specification at ¶ [0005].

services, etc.) within a bill.[3] Typically, this would require a variety of people within different disciplines. Next, a clinician would be required to ascertain and retrieve those regulatory guidelines (e.g., Medicare, Medicaid, CMS, other public regularly guidelines, and/or guidelines generated by private companies) that apply to each of the billing items of a particular bill. The clinician would then have to compare the guidelines and the billing items to make a determination, to the best of their ability, whether each billing item is compliant. Accordingly, due to the labor intensity of manually determining compliance, deficiencies are only spotted on those bills within a selected sample that are inspected during an internal audit.[4] In contrast, the invention recited in claims 1 and 23 provides an automated tool for accurately checking each bill for compliance with regulatory guidelines; thus, potentially catching any deficiencies in every bill sent out to patients.

The Fitzgerald reference does not disclose a process for determining compliance of a preliminary billing item that includes comparing the preliminary billing item against a compliance template that has the features of (i) criteria configured based on the preliminary billing item and at least one regulatory guideline, and (ii) data fields, which correspond to each of the criteria, respectively, that record information that satisfies the criteria. Instead, Fitzgerald evaluates claim data—related to provision of healthcare—for accuracy by using rules to validate the claim data for processing payment.[5] However, these rules are not comparable to the positively claimed structure of the compliance template and they are not customized according to the contents of a particular preliminary billing item. Moreover, the rules are not selected based on both (a) the preliminary billing item and (b) at least one regulatory guideline, but generally

[3] *Id.* at ¶¶ [0023] and [0024].
[4] *Id.* at ¶ [0006].
[5] *See Fitzgerald reference* at pg. 3, ¶ [0025].

derived from a repository. As such, for at least this reason, the Fitzgerald reference does not teach each and every element of the independent claims 1 and 23.

Accordingly, the Applicant contends that claims 1 and 23 are not anticipated by Fitzgerald and are in condition for allowance. Each of claims 4, 6, 7, 9-11, 15-22 and 26-38 is believed to be in condition for allowance based, in part, upon their dependency from claims 1 and 23, respectively, and such favorable action is respectfully requested.[6]

Further, independent claims 1, 12, and 23 are amended to recite a step of verifying the existence of supporting data upon the preliminary billing item failing to comply with a regulatory guideline. For example, claim 1 recites a "conditioning engine [that] is further configured for, upon determining that the preliminary billing item is insufficient to satisfy the at least one regulatory guideline, *automatically searching within a clinical data store to verify the existence of computerized data that supports the preliminary billing item*" (emphasis added). In this way, a search for specific computerized data is conducted by the conditioning engine (supported by the processing unit) upon the trigger of determining that the preliminary billing item is insufficient.

Anticipation "requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee."[7] "[P]rior knowledge by others requires that all of the elements and limitations of the claimed subject matter must be expressly or inherently described in a single prior art reference."[8] "The single reference must describe and enable the claimed invention, including all claim limitations,

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[6] *See* 37 C.F.R. § 1.75(c) (2006).

[7] MPEP § 2131, *passim*; *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302 (Fed. Cir. 1995).

[8] *Elan Pharms., Inc. v. Mayo Foundation for Medical Educ. & Research*, 304 F.2d 1221, 1227 (Fed. Cir. 2002) (citing *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988)).

with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention."[9]

The Examiner states that Fitzgerald does not teach affirming data elements that provide a record of services delivered.[10] U.S. Patent No. 4,858,121 to Barber (hereinafter Barber) fails to cure this deficiency of Fitzgerald. In particular, Barber does not teach or suggest "automatically searching within a clinical data store to verify the existence of computerized data that supports the preliminary billing item" "upon determining that the preliminary billing item is insufficient to satisfy the at least one regulatory guideline." Rather, the cited portion of Barber simply teaches retrieving information from a library, such as "patient identification, insurance company, and medical treatment."[11] First, this information is not retrieved in response to a determination that the preliminary billing item is insufficient to satisfy regulatory guideline(s). Second, the information sought in Barber is distinct from computerized data that supports the preliminary billing item. Accordingly, the Applicants contend that claims 1, 12, and 23 are not unpatentable in view of the combination of Fitzgerald and Barber.

Further, in the present hospital context, manually performing the process of searching within a clinical data store to verify the existence of computerized data that supports the preliminary billing item is impractical due to the inaccessibility and broad distribution of the computerized data. For instance, the clinician would be required to search databases and other data sources, review logs or records from various health care departments, scan for updated patient account numbers, and the like.[12] Accordingly, utilizing the conditioning engine to

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[9] *Id.* (emphasis added)(citing *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002); *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990)). *See also, PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).
[10] Office Action at pg. 17.
[11] *See Barber reference* at col. 5, ll. 50-55.
[12] *See* Specification at ¶¶ [0031] and [0034].

automatically search within a clinical data store to verify the existence of computerized data that supports the preliminary billing item, as claimed, involves extra steps and rapidly searches multiple locations that a human would not be able to perform.

Rejections based on 35 U.S.C. § 103

A.) Applicable Authority

The teachings or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure.[13] To establish a *prima facie* case of obviousness, all the claim limitations must be taught by the prior art.[14] "All words in a claim must be considered in judging the patentability of that claim against the prior art."[15]

B.) Unpatentable Rejection Over Fitzgerald in view of Barber

Claims 4, 7, 9, 12, 15-22, 30, 31, 34, and 35 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Fitzgerald in view of Barber. As discussed above, neither Fitzgerald nor Barber teach or suggest all of the limitations of the pending independent claims 1, 12, and 23, from one of which each of rejected claims 4, 7, 9, 15-22, 30, 31, 34, and 35 depends, either directly or indirectly. Accordingly, it is respectfully submitted that the Fitzgerald and

[13] *See* MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).
[14] MPEP § 2143.03; *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974).
[15] MPEP § 2143.03; *In re Wilson*, 57 C.C.P.A. 1029, 1032 (1970)

Barber references, whether taken alone or in combination, fail to teach or suggest all of the limitations of the claims 4, 7, 9, 12, 15-22, 30, 31, 34, and 35.[16]

[16] *See* 37 C.F.R. § 1.75(c) (2006).

CONCLUSION

For at least the reasons stated above, each of claims 1, 4, 6, 7, 9-12, 15-23, and 26-38 is believed to be in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned—by telephone at 816.559.2136 or via email at btabor@shb.com (such communication via email is herein expressly granted)—to resolve the same prior to issuing a subsequent action.

It is believed that no fee is due in conjunction with the present communication. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.110509.

Respectfully submitted,

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